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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Tsutomu Okada

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SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,672	Applicant(s) OKADA, TSUTOMU	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/25/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-27, 29-32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27, 29-32 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 06/25/2008.

The examiner acknowledges the amendments made to the claims.

Claim Objections

1. Claims 24-27, 30-32, 34, and 36 are objected to because of the following informalities: All the claims begin with "A clip" and should rather read --The clip--.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 23-26, 29-32, 34-35, 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al., hereinafter "**Kobayashi**" (U.S. Patent No. **7,011,667**) in view of **Matsui et al.**(U.S. Patent No. **6,352,503**).

Kobayashi disclose a flexible insertion tube **1** capable of being inserted into a cavity, a flexible single wire **9** having pliability and movable through the insertion tube, a junction provided on a distal end portion of the wire, detachably coupled with a clip **3** located at the distal end portion of the insertion tube for effecting grasping operation and disengaging operation of the clip, wherein the junction is pliable enough to follow substantial bending deformation of the insertion tube, such that movement in the tube is

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not hindered by the bending deformation, the junction adapted to break when the wire when the wire is hauled with a tractive effort great enough to leave the clip and the junction includes a looped flexible wire **10** of predetermined length, one end which is coupled with the clip and a coupling member or joint (looped end of **9**) connected to the flexible wire, the coupling member having a detachable coupling with the looped flexible wire, wherein the looped flexible wire is deformable to be released from the coupling member (Figures 7A-7C). A flexible insertion tube **11** forms a push member for advancing the clip (Figure 7D).

Although multiple clips rather than a "single clip" is disclosed in Kobayashi, it would have been obvious to one of ordinary skill in the art to provide just a single clip if the intended surgery only requires one clip.

Kobayashi does not disclose the coupling member having a deformable portion being deformable to release the looped flexible wire so that the junction is broken, but rather the opposite as mentioned above, wherein the looped flexible wire **10** breaks or deforms to release itself from the coupling member (col. 8, lines 34-42). However, it would have been obvious to one of ordinary skill in the art at the time of invention to make the coupling member (looped end of **9**) breakable to detach from the looped flexible wire **10**, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art.

In addition, Kobayashi does not disclose a curved portion at the distal end portion of the flexible insertion tube or having the looped flexible wire at a certain length wherein the coupling member does not enter the curved portion of the flexible insertion

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tube when one end of the looped flexible wire is released from the distal end portion of the flexible insertion tube.

Matsui et al. teach a distal end part of an insertion tube forming a curvedly raised portion, such as in use with a side-viewing endoscope, wherein the curvedly raised portion is bent up to substantially 90 degrees by a forceps raising device (Figures 48-50). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a curvedly raised insertion tube portion, as taught by Matsui, to Kobayashi since it was well known in the art to provide a curvedly raised tube in the use of side-viewing type endoscopes to effectively treat a region of interest by front-viewing the region located in a hard-to-front-view position (col. 18, lines 40-45). Depending on the length of the looped flexible wire **10** (as seen in varying lengths in Figures 23A-26D of Kobayashi), it appears that the coupling member **9** would not enter the curved portion of the insertion tube of Matsui et al. However, it may have occurred to one of ordinary skill in the art to vary the length of looped flexible wire **10** in order to increase flexibility and prevent inadvertent breaking of the junction, and discovering an optimum dimension for an element involves only routine skill in the art.

Kobayashi does not expressly disclose a flexible tube sheath penetrated by the insertion tube. However, flexible introducer sheaths are commonly used in the art to facilitate introductions of tubular members to protect the body lumen as well as the introduction into endoscopes, and therefore it would have been obvious to one of ordinary skill in the art to modify Kobayashi with the addition of a flexible tube sheath.

Lastly, Kobayashi does not expressly disclose coupling member **9** having greater rigidity than looped flexible wire **10**, but it would have been obvious to one of ordinary skill in the art at the time of invention to provide a material with greater rigidity to elements proximal to the looped flexible wire to increase control of the device when the push member extrudes the clip distally.

4. Claims 27 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kobayashi** (U.S. Patent No. **7,011,667**) in view of **Matsui et al.** (U.S. Patent No. **6,352,503**), as applied to claim 23 above, and further in view of **Matsuno et al.** (U.S. Patent No. **5,766,184**).

Kobayashi and Matsui et al. disclose the claimed device except for the deformable portion being J-shaped.

Matsuno et al. teach a J-shaped deformable portion **51** for releasing a clip member (Figures 5A, 15B-15C; col. 12, lines 53-60). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a J-shaped deformable portion, as taught by Matsuno et al., to Kobayashi in order to facilitate deformation of the coupling member when pulling on the wire and since hook-shaped members are old and well known in the art.

Response to Arguments

5. Applicant's arguments with respect to claims 23-27, 29-32, and 34-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734